Comments on Formaldehyde Expert Panel Report – Part A James A. Swenberg, D.V.M., Ph.D. Kenan Distinguished Professor University of North Carolina

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I have read the Expert Panels Report and offer the following comments.

Section 4.1, P12 comment on pp. 281-282: The nasal tumors did not occur at the "end of the nose." They occurred in the respiratory epithelium, with the anterior lateral meatus being the site within the respiratory epithelium with the highest incidence. This is clearly described in the Monticello, et al, 1996, Cancer Research paper.

Section 4.1, P13: The reference to Nelson regarding bone marrow hyperplasia has been used with selective quotation that suggests a very different conclusion. The actual statement is "Bone marrow hyperplasia present in the rat bioassay was not considered a primary effect of formaldehyde exposure, but secondary to anoxia due to the presence of obstructive masses in the nasal passages."

Section 5.4.2.4, P 21: The methods reported in the paper by Zhang et al (2010) do not permit differentiating between the chromosomal changes (monosomy and trisomy) being induced *in vivo* or *in vitro*. Thus it cannot be concluded that they were present in the exposed workers. Rather, it must be qualified to state that they were only measured in cultured cells.

Section 5.6.4.3, P 23: The second bullet requesting citation of Zhang et al (2010) must also be qualified.

Section 5.8.5 Summary, P 24: We have submitted a manuscript (Lu et al, *Toxicological Sciences*, 2010) that is in press along with these comments that presents exposure specific data demonstrating that inhaled formaldehyde does not reach sites distant from the portal of entry. This paper contains the only data that are chemical specific on this subject and greatly challenges the Panel's conclusion. The data on smokers (Wang et al, 2009) is not from inhaled formaldehyde, but rather from formaldehyde arising from metabolism of nitrosamines and NNK. This is discussed in Lu et al, *Toxicological Sciences*, 2010. The other studies cited (Pala. Shaham and Zhang) are not chemical specific.